



## MEMORANDUM

DATE: March 7, 2005

FROM: William Freas, Ph.D. *Will Freas*  
Director, Division of Scientific Advisors and Consultants

TO: Sheila Dearybury Walcott, Esq.  
Associate Commissioner for External Relations  
Food and Drug Administration

SUBJECT: Waiver of General Applicability Under 18 U.S.C. 208(b) (3)  
For Catherine S. Manno, M.D.

THROUGH: Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office of Management Programs, OM

I am writing to request a general matters waiver for Catherine S. Manno, M.D., a member of the Blood Products Advisory Committee at the March 17-18, 2005 meeting. This memorandum constitutes a determination that the need for Dr. Manno's services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial interest that she may have in matters of general applicability in which she is expected to participate on the Committee. 18 U.S.C. 208(b) (3).

The Committee will review and evaluate available scientific data concerning the safety, effectiveness, and appropriate use of blood intended for use in the diagnosis, prevention, or treatment of human diseases. During the March 17-18, 2005 meeting, the Committee will discuss the safety of albumin, review of standard for plasma products for transfusion, and the study design for the abbreviated donor history questionnaires.

The Committee will be discussing matters for general applicability, as opposed to matters involving specific parties or matters that uniquely and distinctly affect any particular person or organization. These matters may affect certain financial interest of Dr. Manno's or of persons and organizations with which she may have certain relationships. This would include:

Financial investments in medical product companies, food related companies, drug related companies, health care industry, and any other industry that might be affected by the recommendations of the Committee (no interest currently reported);

**Page 2 – Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for External Relations  
Food and Drug Administration**

**Employment with research institutions, state and local governments, medical product manufacturers, food related companies, drug related companies, health care industry or other organizations that may be affected by the Committee's for example, the Children's Hospital of Philadelphia where she is employed, and her consulting with [REDACTED] to the preparation of a manuscript on plasma-derived prothrombin complex concentrate;**

**Grants, contracts or other funding for research or other services received from the federal government that might be affected by the Committee's recommendations (no interests currently reported);**

**Grants contracts or other funding for research or other services received from non-federal sources, including industry and foundations, that might be affected by the Committee's recommendations, for example, her two contracts supported by [REDACTED] for recombinant F. VIII.**

**Expert witness, litigation or advocacy services in matters that might be affected by the recommendations of the Committee (no interest currently reported);**

**Any interest of a group or other organization in which Dr. Mann is appointed as an officer, director, trustee, employee or general partner that might be affected by the Committee's recommendations (no interest currently reported);**

**Under 18 U.S.C. 208, Dr. Manno may not participate in any particular matter affecting these interests, unless she receives a waiver. However, pursuant to my authority to grant waivers under 18 U.S.C. 208(b) (3), I have determined that the need for the services of Catherine S. Manno on this Committee, with respect to matters of general applicability, outweighs any concern that these types of interest might create a potential for a conflict of interest. Consequently, Dr. Manno may participate in matters of general applicability affecting any current and future financial interest of the types described above. This determination is based on the following considerations:**

**The Food and Drug Administration has a particularly strong need for Dr. Manno's services. Dr. Manno is Associate Professor of Pediatrics, The Children's Hospital of Philadelphia. She is board certified in hematology and oncology. Dr. Manno serves as a special advisor to the chairman of the medical and scientific advisory committee of the National Hemophilia Foundation (NHF) which is one of the constituent of the BPAC.**

Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgeable in a variety of scientific and medical professions. Consequently, it is expected that persons qualified to serve on the Committee will have interests, financial and otherwise, in the work of the Committee. This includes not only employment interests, but also investment and pension interests, as experience has shown that persons employed in the biomedical area frequently acquire investment and pension interests in organizations related to their expertise. In short, financial interests simply are unavoidable in view of the work and membership requirements of this Committee.

Likewise, the very diversity of interests required by the Charter will ensure that no one member is in a position to determine policy in favor of any one affected interest. In addition to the specific requirements of the Charter, the Federal Advisory Committee Act requires fair balance and openness, which serve as important checks against real or apparent threats to the objectivity of Committee action.

Finally, the Committee is expected to focus mainly on matters of general applicability, rather than matters involving specific parties. It is well-recognized that such general matters pose less risk of a conflict of interest. Matters of general applicability include regulations, legislation, and policies governing classes of organizations, individuals, and products.

However, this does not include matters involving specific parties, such as specific grants (as opposed to general recommendations for increased funding in a given area), contracts, product approval applications, or enforcement matters involving known parties.

Please note that this waiver is limited to general matters. It will not allow Dr. Manno to participate in any matters involving specific parties that may affect her financial interests, or any

Page 4 – Sheila Dearybury Walcott, Esq.  
Associate Commissioner for External Relations  
Food and Drug Administration

person or organization described above. If the work of the Committee turns from matters of general applicability to more specific matters (e.g., recommendations regarding a specific product), participants will seek additional advice.

CONCURRENCE:

Jenny Slaughter  
Jenny Slaughter, Director  
Ethics and Integrity Staff  
Division of Management Programs, OM

3/9/05  
Date

DECISION:

X  
General Matters Waiver granted based on my determination, made in accordance with section 208(b) (3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

         Waiver denied.

Sheila Dearybury Walcott  
Sheila Dearybury Walcott, Esq.  
Associate Commissioner for External Relations, FDA

          
Date